

Application No.: 10/634,213
Filing Date: August 5, 2003

REMARKS

This paper is responsive to the Examiner's Office Action of April 4, 2008. By way of summary, Claims 5, 7-9, 11, 27, 28, 37 and 53-73 were pending in the application. Applicants have hereby amended the Title, Specification, Abstract, and Claims 5, 27, 28, 53, 60, 61, 66 and 73, and added new Claims 74-76. Thus, Claims 5, 7-9, 11, 27, 28, 37 and 53-76 are presently pending in this application. Reconsideration of the application in view of the foregoing amendments and following remarks is respectfully requested.

The specific changes to the written description and any amended claims are shown by strikethrough or double bracketing for any deletions, and underlining for any insertions.

Amendments to the Title, Specification and Abstract

As shown above, the Title and Abstract of the Disclosure have been amended. Support for these amendments can be found in the Application as originally filed. No new matter has been introduced. Accordingly, Applicants request entry of these amendments.

Paragraph number [0001] of the Specification has been amended, as shown above, to update the status of a priority application which has issued as U.S. Patent No. 7,135,009 B2.

As also shown above, a paragraph has been added to the Specification at the beginning of the section entitled "Summary of the Invention." This paragraph has been bodily incorporated from priority Application No. 10/118,578 (now U.S. Patent No. 7,135,009 B2), which is incorporated by reference by the present application (at paragraph number [0001] of the Specification), and corresponds to column 4, lines 10-17 of the '009 patent. It is respectfully submitted that no new matter has been introduced. Accordingly, Applicants request entry of this amendment.

Claims 5, 7-9, 11, 27, 28, 37 and 53-73 are Patentable Over the Applied Combination

The Examiner rejected Claims 5, 7-9, 11, 27, 28, 37 and 53-73 under 35 U.S.C. § 103(a) as being obvious in view of the combination of U.S. Patent Nos. 5,968,058 and 6,450,937 to Richter et al. ("Richter") and Mercereau et al. ("Mercereau") respectively.

Applicants respectfully traverse these rejections and the Examiner's characterization of the cited references on the bases set forth below.

As shown above, Claims 5, 53, 60, 61 and 66 have been amended for antecedent basis purposes, Claims 27 and 28 have been amended to change the respective preambles, and Claim 73 has been amended to correct a minor typographical error.

To Applicants' knowledge, the benefits of multiple implantations in an eye were neither known or appreciated by others of skill in the art prior to Applicants' disclosure. For example, paragraph number [0331] of the Specification as filed states (emphasis added):

The term "targeted placement" of trabecular stents refers to the **intentional placement of a stent at a particular location** in Schlemm's canal for the purpose of providing a maximum benefit in the form of maximum outflow facility. ...

At a minimum, neither of the two applied references, Richter and Mercereau, appreciated the advantage of multiple implants for treating an ocular disorder.

Richter discloses an ophthalmic implant, a single-implant delivery device, and a method of implanting a single implant. Mercereau discloses a brachytherapy needle for delivering radioactive seeds into the body of a patient. The Examiner asserted that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Richter with Mercereau to achieve the benefits of multiple implantation in an eye as set forth in Applicants' claims.

Applicants' respectfully disagree with the Examiner's assertion. There is no evidence that Richter contemplated implanting multiple implants in the eye. Richter clearly teaches that a single implant will achieve the stated objective of lowering intraocular pressure (IOP). Richter additionally notes the problems associated with lowering IOP too much. See, e.g., Col. 1, ll. 35-38. Richter further teaches forming a flap in the conjunctiva and piercing through the sclera at a location just to the anterior side of the iris. In view of degree of trauma caused during implantation and the unambiguous teaching that a single implant will sufficiently lower IOP to treat glaucoma without creating a hypotonic condition, one skilled in the art would not have read Richter to teach or suggest the use of multiple implants, as the Examiner seems to suggest.

Additionally, there is no evidence that Richter contemplated a delivery device to hold multiple implants. Richter's design requires specific structural features between the single-implant and the delivery device so as to couple them together during implantation. These features appear to inhibit the delivery device from delivering more than one implant at a time. In

particular, as best seen in Figures 8 and 9 of Richter, the implant is not positioned within the device, and Richter further teaches applying a force, which is necessary to drive the implant through the sclera. to the angled disk (34). The Richter delivery device consequently would require a substantial design change in order to delivery multiple implants, and such design change would be well beyond the design disclosed in Mercereau, which utilizes a push stylet (16) to expel the radioactive seeds. Accordingly, Applicants submit that the Examiner has failed to establish a *prima facie* showing of obviousness.

In addition to the combination of Richter and Mercereau being improper – as there exists no sustainable reason in the record to combine these references together and the teaching of these references would clearly lead one skilled in the art away from making the suggested combination – the references fail to teach or suggest one or more limitations of the pending claims. With respect to Richter, the Examiner asserted at page 3, lines 2-10 of the Office Action:

The instrument (Fig. 13) comprises a trocar (164) with a cutting edge sufficiently sharp to cut through Schlemm's canal and a biocompatible implant (130) with a cutting edge (158), where the implant is sized to convey aqueous humor from the anterior chamber to fluid outflow path of the eye so as to reduce elevated intraocular pressure (col 2, ln 48-57). The method comprises using the instrument to deliver the implant through a wall of Schlemm's canal, which extends from the sclera into the anterior chamber of the eye (col 5, ln 5-14). The delivery location is determined by imaging collector channel locations (col 3, ln 35-43).

Contrary to this statement, there is no mention or suggestion in Richter of placing the implant into Schlemm's canal or into any other physiologic outflow pathway. Richter further unquestionably fails to teach that the needle (160) is capable or suitable for cutting Schlemm's canal. Richter additionally fails to teach or suggest implanting through a wall of Schlemm's canal or other physiologic outflow pathway.

Moreover, the implant element (158) of Richter is a retention flange or anchor and not a cutting edge of the implant (see column 8, lines approx. 5-9, and 47-53 of Richter). Applicants would also like to point out that Richter's implant drains to a "bleb" or "artificially-created site" and not to a physiologic outflow pathway of the eye, such as, Schlemm's canal (see Abstract lines 8 and 9, and column 6, lines approx 30-35 of Richter).

Applicants also respectfully note that there is no teaching in suggestion in Richter of determining a delivery location by “imaging collector channel locations,” as required by some of the rejected claims. The Examiner pointed to column 3, lines 35-43 of Richter for support of this claimed limitation. However, this text refers to providing a marker on the implant. This has no relationship or relevance to imaging collector channel locations. These channels are aqueous humor draining ducts associated with the eye (see, for example, paragraph number [0005], and the last 2 lines of paragraph number [0051] of the Specification as filed).

With respect to Mercereau, the Examiner asserted at page 3, lines 11-16 of the Office Action:

Mercereau et al. disclose a device for delivering implants to selected body tissue comprising an outer tubular elongate body (12) surrounding a trocar (14) and implant (50). Mercereau et al. teach the outer tubular elongate body comprises a cutting edge (20) for piercing the tissue and forming a bore for delivery of the implant. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Richter et al. to include an outer tubular elongate body with a cutting edge surrounding the trocar and implant.

Applicants respectfully disagree with the Examiner that Mercereau discloses an outer tubular elongate body that surrounds a “trocar.” As is known in the art, a trocar is a sharp-pointed surgical instrument typically used for cutting or penetrating tissue. Applicants disclose a trocar in the Application as filed. For example, at paragraph numbers [303] and [0322], and FIGS. 52A-52D, 53A and 54B disclose trocars or cutting members 250 (with cutting tip 247), 264.

As disclosed at various instances, Mercereau teaches a hollow cutting cannula (12) with a beveled cutting edge (20) and a seed carrier (14) disposed within the cutting cannula (12). See, Abstract lines 1-4, column 2, lines approx. 44-47, column 4, lines approx. 13-16, and column 6, lines 50 and 52, of Mercereau. The cutting cannula (12) may be considered a trocar since it has a cutting edge (20). However, the seed carrier (14) does not, and is hence clearly not a trocar. Thus, Mercereau fails to teach or suggest a trocar in or within an elongate body or tube as claimed by Applicants.

The Examiner also asserted that Richter could be modified by Mercereau to deliver multiple implants without removal of the delivery device from the eye between implant deliveries. By merely looking at Richter's implant structure, and its implantation with the implant's angled disk (34) resting on the outer surface of the sclera (12), it would be clear to one of ordinary skill in the art that such multiple deliveries would not be possible by combining Richter and Mercereau, as explained above. Moreover, Mercereau teaches that the seeds (50) can only be delivered in a column (54) by a single needle. Given these limitations, it is unclear where, how and why a second implant of Richter would be positioned in the eye to perform its function without removal of the delivery device between deliveries.

The Examiner further asserted at page 4, lines 12-17 of the Office Action:

... the prior art does not specifically teach first and second implants are delivered to first and second locations that are angularly spaced at least 20 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Mercereau et al. such that when multiple implants were used, first and second implants were spaced at least 20 degrees ...

Applicants respectfully disagree with this assertion by the Examiner. As indicated above, the benefits of targeted implantation in an eye were neither known nor appreciated by others of skill in the art prior to Applicants' discovery thereof. For example, paragraph number [0251] of the Specification as filed states (emphasis added):

The programmed (also know as "Targeted") stent placement refers to the **intentional placement of a stent or stents at a particular location or locations in Schlemm's canal** for the purpose of providing a benefit in the form of more optimal outflow.

Applicants discovered the benefits achieved, in some cases, by providing a predetermined angular spacing, in one embodiment of at least 20 degrees, between implantation sites that was not recognized by others of skill in the art. Thus, Applicants submit that the claims directed to this subject matter are not rendered obvious by the prior art, including the applied combination.

Turning now to the specific claims, independent Claim 5 is directed to an instrument for delivering implants for treating an ophthalmic condition and dispensing implants through a wall of Schlemm's canal, and recites, *inter alia* (emphasis added):

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an elongate body, said elongate body comprising a tube sized to be introduced into an eye through an incision in the eye;

a trocar in said tube, wherein said trocar has a cutting edge sufficiently sharp to cut through said wall of Schlemm's canal;

a plurality of biocompatible implants positioned in the elongate body.

As discussed above, this, among other things, these structural limitations are not taught or suggested by the applied references, individually or collectively. Thus, Claim 5 is patentable over the applied combination.

Claims 7-9 and 11 depend from Claim 5 and are patentable for at least the same reasons that Claim 5 is patentable, and because of the unique combination of features recited therein. Moreover, these claims define over the prior art, since the combination of features recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claims 5, 7-9 and 11 are in condition for allowance.

Independent Claim 27 is directed to a method of implanting a plurality of implants for treating an ocular disorder and recites, *inter alia* (emphasis added):

utilizing said instrument to **deliver a first implant** through a wall of Schlemm's canal at a first location; and

utilizing said instrument to **deliver a second implant** through a wall of Schlemm's canal at a second location;

wherein said **locations are determined by imaging collector channel locations.**

As discussed above, these steps, among others, are not taught or suggested by the applied references individually or collectively. Thus, Claim 27 is patentable over the applied combination.

Claim 37 depends from Claim 27 and is patentable for at least the same reasons that Claim 27 is patentable, and because of the unique combination of features recited therein. Moreover, these claims define over the prior art, since the combination of features recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

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Accordingly, Applicants respectfully submit that Claims 27 and 37 are in condition for allowance.

Independent Claim 28 is directed to a method of implanting a plurality of implants for treating an ocular disorder and recites, *inter alia* (emphasis added):

utilizing said instrument to **deliver a first implant** through a wall of Schlemm's canal at a first location; and
utilizing said instrument to **deliver a second implant** through a wall of Schlemm's canal at a second location;
wherein said **locations are angularly spaced along Schlemm's canal by at least 20 degrees.**

As discussed above, these steps, among others, are not taught or suggested by the applied references, individually or collectively. Thus, Claim 28 is patentable over the applied combination. Moreover, this claim defines over the prior art, since the combination of features recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claim 28 is in condition for allowance.

Independent Claim 53 is directed to an instrument for delivering implants for treating an ophthalmic condition and dispensing implants through a wall of Schlemm's canal, and recites, *inter alia* (emphasis added):

an elongate body, said elongate body sized to be introduced into an eye through an incision in the eye;
a **plurality of biocompatible implants positioned in the elongate body ...**
wherein at least one of said **implants comprises a cutting member.**

As discussed above, these structural limitations, among others, are not taught or suggested by the applied references individually or collectively. Thus, Claim 53 is patentable over the applied combination.

Claims 54-59 depend from Claim 53 and are patentable for at least the same reasons that Claim 53 is patentable, and because of the unique combination of features recited therein. Moreover, these claims define over the prior art, since the combination of features recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claims 53-59 are in condition for allowance.

Independent Claim 60 is directed to an instrument for delivering implants for treating an ophthalmic condition and dispensing implants through a wall of Schlemm's canal, and recites, *inter alia* (emphasis added):

an elongate body, said elongate body comprising a tube being sized to be introduced into an eye through an incision in the eye;

a trocar being disposed within and being axially moveable through said tube, wherein said trocar has a cutting portion sufficiently sharp to cut through said wall of Schlemm's canal;

a plurality of biocompatible implants positioned in the elongate body.

As discussed above, these structural limitations, among others, are not taught or suggested by the applied references, individually or collectively. Thus, Claim 60 is patentable over the applied combination. Moreover, this claim defines over the prior art, since the combination of features recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claim 60 is in condition for allowance.

Independent Claim 61 is directed to an instrument for delivering implants for treating an ophthalmic condition and dispensing implants into tissue adjacent to a physiologic outflow pathway, and recites, *inter alia* (emphasis added):

an elongate body comprising a tube sized to be introduced into an eye through an incision in the eye;

a trocar in said tube, said trocar having a cutting portion sufficiently sharp to form an opening in the tissue adjacent said physiologic outflow pathway; and

a plurality of biocompatible implants positioned in the elongate body, each of said implants sized and shaped to **convey aqueous humor from an anterior chamber of the eye to the physiologic outflow pathway of the eye.**

As discussed above, these structural limitations, among others, are not taught or suggested by the applied references individually or collectively. Thus, Claim 61 is patentable over the applied combination.

Claims 62-65 depend from Claim 61 and are patentable for at least the same reasons that Claim 61 is patentable, and because of the unique combination of features recited therein. Moreover, these claims define over the prior art, since the combination of features recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claims 61-65 are in condition for allowance.

Independent Claim 66 is directed to a method of implanting a plurality of implants for treating an ocular disorder and recites, *inter alia* (emphasis added):

providing a plurality of biocompatible implants that, when implanted, convey aqueous humor from an anterior chamber of the eye to a physiologic outflow pathway of the eye; utilizing said instrument to deliver a first biocompatible implant through a wall of a physiologic outflow pathway at a first location within the eye; and utilizing said instrument to deliver a second biocompatible implant through a wall of said physiologic outflow pathway at a second location within the eye, without removing said instrument from the eye between said deliveries of said implants.

As discussed above, these steps, among others, are not taught or suggested by the applied references individually or collectively. Thus, Claim 66 is patentable over the applied combination.

Claims 67-73 depend from Claim 66 and are patentable for at least the same reasons that Claim 66 is patentable, and because of the unique combination of features recited therein. Moreover, these claims define over the prior art, since the combination of features recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claims 66-73 are in condition for allowance.

New Claims 74-76 Define Over the Prior Art

Applicants have added new Claims 74-76 to vary further the scope of protection. These claims are supported by the Application as originally filed, and no new matter has been introduced.

Independent Claim 74 is directed to a method of implanting a plurality of implants for treating an ocular disorder and recites, *inter alia* (emphasis added):

utilizing the instrument to **deliver a first implant** through eye tissue so as to place a portion of the first implant in a uveal scleral outflow path of the eye; and

utilizing the instrument to **deliver a second implant** through eye tissue so as to place a portion of the second implant in the uveal scleral outflow path, **without removing the instrument from the eye between the deliveries of the implants.**

At least these limitations are not taught or suggested by the applied references, individually or collectively.

Claims 75 and 76 depend from Claim 74 and are patentable for at least the same reasons that Claim 74 is patentable, and because of the unique combination of limitations recited therein. Moreover, these claims define over the prior art, since the combination of limitations recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claims 74-76 are in condition for allowance.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not

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reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicants wish to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed	Attorney Docket No.
10/782,382	GLAUCOMA IMPLANT KIT	February 19, 2004	GLAUKO.1C2C2
11/126,868	INJECTABLE TRANSFORMABLE IMPLANT AND METHODS THEREOF FOR OCULAR DISORDER TREATMENT	May 11, 2005	GLAUKO.1C3CP2
11/124,440	METHOD OF DELIVERING AN IMPLANT FOR TREATING AN OCULAR DISORDER	May 6, 2005	GLAUKO.1C4C2
11/121,584	IMPLANTS FOR TREATING OCULAR DISORDERS	May 4, 2005	GLAUKO.005C1C1
10/950,175	IMPLANT WITH INTRAOCULAR PRESSURE SENSOR FOR GLAUCOMA TREATMENT	September 24, 2004	GLAUKO.5C1CP1
11/598,542	IMPLANT AND METHODS THEREOF FOR TREATMENT OF OCULAR DISORDERS	November 13, 2006	GLAUKO.011C1
12/111,033	SYSTEM FOR TREATING OCULAR DISORDERS AND METHODS THEREOF	April 28, 2008	GLAUKO.011C1C1
11/836,106	DEVICES AND METHODS FOR GLAUCOMA TREATMENT	August 8, 2007	GLAUKO.11CP1C1
11/836,112	DEVICES AND METHODS FOR GLAUCOMA TREATMENT	August 8, 2007	GLAUKO.11CP1C2
11/084,314	INJECTABLE GLAUCOMA IMPLANTS WITH MULTIPLE OPENINGS	March 18, 2005	GLAUKO.11CP2CP1
11/083,713	OCULAR IMPLANTS WITH ANCHORS AND METHODS THEREOF	March 18, 2005	GLAUKO.011CP3
11/455,598	GLAUCOMA STENT SYSTEM	June 19, 2006	GLAUKO.017C1
11/455,391	GLAUCOMA STENT SYSTEM	June 19, 2006	GLAUKO.017C2

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Serial Number	Title	Filed	Attorney Docket No.
11/332,746	FLUID INFUSION METHODS FOR OCULAR DISORDER TREATMENT	January 12, 2006	GLAUKO.020C1
10/667,580	OCULAR IMPLANT WITH ANCHOR AND MULTIPLE OPENINGS	September 22, 2003	GLAUKO.035A
10/860,785	COIL IMPLANT FOR GLAUCOMA TREATMENT	June 2, 2004	GLAUKO.051A
11/938,238	UVEOSCLERAL SHUNT AND METHODS FOR IMPLANTING SAME	November 9, 2007	GLAUKO.099A

Conclusion

Applicants respectfully submit that the claims are in condition for allowance in view of the above remarks. Any remarks in support of patentability of one claim, however, should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although amendments may have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby. Applicants also reserve the right to later contest further whether a proper reason exists to combine these references as well as to later present facts and arguments supporting the non-obviousness of the claimed subject matter.

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Applicants have made a good faith effort to respond to the outstanding Office Action. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is cordially invited to contact Applicants' attorney, at the telephone number below, to resolve any such issues promptly. Also, please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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